MARYLAND
Health Care
Commission

Randolph S. Sergent, Esq., Chairman
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January 26, 2023

Re: COMAR 10.24.01 Draft Regulations

The Maryland Health Care Commission ("MHCC" or "Commission") released proposed amendments to its procedural regulations, COMAR 10.24.01 *et seq*, for informal review and comment on July 26, 2022 ("Draft Regulations"). The Commission received thirteen submissions, which will be posted separately as Appendix A. This memorandum outlines the high interest areas raised by the commenters and the reasoning why the drafted language was retained or revised. The Commission is re-releasing the proposed amendments ("Revised Draft") for a second round of informal review. **MHCC will hold an interactive webinar session on Thursday, February 9th at 3:00pm to present on the proposed changes to the procedural regulations. Please contact Alexa Bertinelli, Assistant Attorney General, at alexa.bertinelli@maryland.gov if there are any particular themes you would like addressed. Please register in advance at:** https://us02web.zoom.us/meeting/register/tZAocOCtrD0qEtYFOBU57xxtnTAYmeJZCdxe. After you register, you will receive a confirmation email containing information about joining the session.

Following the webinar, MHCC will begin accepting comments on the Revised Draft. Informal comments should be sent to Alexa Bertinelli, AAG, at alexa.bertinelli@maryland.gov no later than February 23, 2023.

I. Background

The impetus for these draft regulations comes from the work of the MHCC CON Modernization Task Force convened in 2017-2018, Governor Hogan's 2015 Regulatory Reform Commission, and the significant changes in the MHCC's enabling statute since COMAR 10.24.01 was last modified in 2005.

In its 2018 Final Report on Modernization of the Maryland CON Program, MHCC identified a number of recommendations for streamlining the CON review process and better aligning it with policy objectives. While many recommendations required statutory changes, some of those areas of modernization could be achieved through changes in COMAR 10.24.01. For example, changes in the draft regulations that raise the threshold for qualifying as an interested party, add flexibility to the performance requirements, use a consent agenda to approve certain project changes, and limit the completeness review process respond to some of the Task Force's recommendations.

The Governor's Regulatory Reform Commission specifically called for the modernization of four health-planning chapters, including the CON procedural regulations.

MHCC made significant changes to the Home Health Agency State Health Plan Chapter (COMAR 10.24.16) in 2016 and the Nursing Home State Health Plan Chapter (COMAR 10.24.20) in 2019. The legislature modified MHCC's oversight of Drug Abuse Intermediate Care Facility Services (ASAM 3.7) in 2019 by allowing established facilities to expand physical bed capacity without CON approval. Even more ambitious efforts by MHCC to fully remove Intermediate Drug Treatment Facilities from CON oversight failed in the General Assembly in 2018 in the face of staunch industry opposition. COMAR 10.24.01 is the last on the Reform Commission's list of MHCC regulations requiring modernization.

Lastly, MHCC's statutory authority over health facility planning and development has been modified several times since the last update of COMAR 10.24.01 in 2005. For example, the General Assembly:

- expanded MHCC's oversight of cardiac services in 2012
- granted MHCC authority to approve the conversion of acute care hospitals to freestanding medical facilities without CON review in 2015;
- changed MHCC's oversight of ambulatory surgery, hospitals, and comprehensive care facilities in 2019, changes grounded in MHCC Report on CON Modernization recommendations; and
- made small changes to MHCC's statute affecting continuing care retirement communities in 2022.

Although COMAR 10.24.01 continues to be serviceable, it makes sense to align this regulation with other regulatory and statutory changes over the past decade.

II. Responses to Comments

a. Definitions

Holder

The Draft Regulations introduced the term "holder," defined as "the applicant or applicants to whom the Commission awarded a Certificate of Need, an exemption from Certificate of Need, or other approval for a project that has not received first use approval nor, if necessary, a license from the Department for that project." The purpose of the new term was to distinguish between the responsibilities of an applicant before and after a CON or other Commission approval has been awarded. The change was also intended to make clear that the post-approval procedures outlined in the regulations apply not just to CON projects, but also projects that are approved as an exemption from CON review under Regulation .04 or as a certificate of conformance under Regulation .13.

MHCC received multiple comments concerning the definition of holder in the Draft Regulations and the application of Regulations .12 (Holder Responsibilities) and .17 (Project

Changes After Commission Approval) to non-CON approvals. The commenters generally urged reconsideration of the application of these post-approval requirements to projects that did not require CON review.

However, projects that are approved as exemptions from CON review are the same types of health care facility projects that require CON review. They have the same scope and impact. The only reason the review process is different is because the applicants are organized as part of multi-facility systems, not because they are smaller or less consequential projects. There is no basis for having different post approval or development monitoring requirements because they are the same projects. Certificate of Conformance reviews are based on the type of project. They are limited to new percutaneous coronary intervention programs. But they are rare and should be held to similar requirements for timely completion and adherence to approved budgets. The current regulations do not have specified procedures for monitoring or approving changes to non-CON projects after Commission approval. As a result, the Commission has applied the procedures specified in Regulations .12 and .17 to projects approved as an exemption from CON review. *See*, *e.g.*, *In the Matter of Conversion of University of Maryland Laurel Regional Hospital to a Freestanding Medical Facility*, Dkt. No. 18-16-EX002 (July 21, 2022). The changes in the Draft Regulations are intended to clarify the Commission's position that the performance standards and the project change process, as well as requests for reconsideration of Commission decisions, should apply equally to CONs and other Commission approvals.

The Revised Draft reflects one small change to the definition of holder to clarify that the definition only applies to those awarded a CON, exemption, or "other ***Commission*** approval." Other Commission approval is a defined term under the Draft Regulations and refers to "approval of a Certificate of Conformance, Certificate of Ongoing Performance, or an exemption from CON review." The change is meant to clarify that the definition of holder is not intended to apply to determinations of coverage, or other authorizations that do not require review by the full Commission.

Adversely Affected

The Commission received multiple comments on the proposed definition of "adversely affected" in the Draft Regulations. "Adversely affected" is used in the procedural regulations for determining whether a person qualifies as an interested party in the review of a CON application. Under the current regulations, a person that is authorized to provide the same services as the applicant in the same or a contiguous planning region meets the definition of "adversely affected" without a showing of any potential negative impact. The revised definition in the Draft Regulations requires a person to also demonstrate that the quality of care of a health care facility the person operates would be materially affected or that the project would result in a substantial depletion of essential personnel or other resources to qualify as an interested party.

Some commenters expressed that the definition was too narrow and left too much authority to a reviewer to determine whether a person qualifies as an interested party. Others urged the Commission to adopt more limiting language to further restrict who may qualify as an interested party.

The revised language in the Draft Regulations gets rid of the presumption that existing providers will be adversely affected by new entrants into the market and instead requires a showing of material negative impact. Existing providers who are recognized as interested parties serve a valuable role and provide an important perspective in evaluating whether a CON application has met all required criteria. However, interested parties obtain significant rights in the review, such as the right to file an appeal of the Commission's decision, and their inclusion in a CON review can delay the review process and limit free economic competition. Staff believes that this definition in the Draft Regulations strikes the right balance.

b. Conditions on non-CON projects

The Commission received multiple comments regarding language in the Draft Regulations that permits the Commission or Commission staff to impose conditions on the approval of non-CON projects, including exemptions from CON review, certificates of conformance or ongoing performance, and determinations of coverage. The Revised Draft has largely removed the ability of staff to impose conditions on determinations of coverage. The exception are projects involving hospital capital expenditures that exceed the hospital capital threshold.

However, the Revised Draft retains the ability of the Commission to impose conditions on exemptions from CON review and certificates of conformance and ongoing performance. The Commission's existing practice is to impose conditions on these types of Commission approval, and the Draft Regulations are merely meant to clarify the Commission's ability to do so. The Commission has broad statutory authority to adopt limits on exemptions from CON review and impose conditions to ensure that projects qualifying for this type of review process are not inconsistent with the State Health Plan, will result in the delivery of more efficient and effective health care services, and are in the public interest. Md. Code Ann., Health-Gen. §§ 19-120; 19-129. As noted previously, with respect to use of the term "holder," projects qualifying for an exemption from CON review process are no different than those that statutorily require CON approval. There is no logic or fairness in allowing conditions on CON-approved projects but not allowing conditions on projects approved through the exemption from CON review process. They are the same projects; only the characteristics of the applicant are different. In general, conditions allow a more flexible approach to regulatory oversight, allowing approvals to go forward on projects that the Commission finds to be generally approvable under the applicable criteria and standards but for which the Commission has concerns with respect to the future of commitments made by the applicant or changes that could be made in the project that would alter its expected impact or operations. With

conditions, the Commission is not faced with a purely binary choice to approve or deny a project.

The statute governing certificates of conformance and ongoing performance specifically require the Commission to impose a condition on the certificates that the hospital voluntary relinquish its cardiac surgery services if it fails to meet applicable standards. § 19-120.1 The statute does not restrict the Commission from imposing additional conditions if necessary.

c. New Review Criteria

The Office of the Attorney General's Health Education and Advocacy Unit (HEAU) proposed new CON review criteria to address health equity, character and competence, and compliance with applicable State and federal laws. Staff determined that a criterion requiring compliance with applicable State and federal laws was too broad and vague for meaningful review and may extend beyond the scope of the Commission's authority under Md. Code Ann., Health Gen. § 19-120. A requirement for an applicant to demonstrate compliance with other State and federal law and regulation may be more appropriate for inclusion in individual State Health Plan Chapters, where the standard could be specifically tailored to the type of facility. In fact, some State Health Plan chapters already require compliance with other State and federal laws. *See, e.g.*, COMAR 10.24.20 (incorporating standards set by the Office of Health Care Quality and Medicaid).

However, the proposed regulations have been amended to add review criteria requiring the Commission to consider how a proposed project will address health care disparities and to assess the applicant's character and competence. A major priority of the Commission is to address health disparities and ensure that all Marylanders have access to quality health care and the information needed to make informed decisions about their care. *See*, Md. Health Care Comm'n, 2021 Annual Report; Md. Code Ann., Health Gen. § 19-103.

Staff also agrees with HEAU that it is important to assess the character and competence of an applicant based upon the applicant's experience and past performance, including any past violations. The Commission's CON applications have long required an applicant to disclose whether it has been subject to prior disciplinary action. While the Commission currently considers an applicant's compliance with a prior CON, this new standard would allow the Commission to consider other violations in rendering its decision.

d. Timeframes and Deadlines

Deemed Approval of Exemption Projects

The Commission's enabling statute provides that the Commission shall act on most requests for exemption from CON review within 45 days of receipt of the facility's request. Md. Code Ann., Health-Gen. § 19-120(h)(2)(iii), (j)(2)(iv) & (k)(6)(v). Commenters requested an amendment that establishes a status reporting requirement that if the Commission fails to act within 45 days, staff shall provide a status report at the next Commission meeting and any subsequent Commission meeting stating the reasons for the delay and the expected time frame for issuing a decision. To increase accountability on timely action on requests, staff adopted the suggested amendment under COMAR 10.24.01.04E(2).

Additionally, commenters requested a contingency if the Commission does not act within the required time frame. The Revised Draft incorporates the suggested amendment which states that an exemption request shall be deemed approved for any project that qualifies under the regulations if final action by the Commissions does not occur within 90 days after the facility has provided compete notice and has held a public hearing as required. See COMAR 10.24.01.04E(3).

Temporary Delicensure

Multiple commenters requested that the Commission eliminate the limit on requesting a temporary delicensure of beds more than one time in a 12-month period. Staff believes the current limit is necessary to ensure oversight of existing licensed bed capacity. MHCC, the Office of Health Care Quality, and other State agencies, maintain inventories of licensed bed capacity. Permitting more frequent requests for temporary delicensure would be difficult to track and monitor.

Completeness Review

The Commission received multiple comments regarding the length and scope of the completeness review. First, commenters sought clarification that an applicant should have 10 business days, not calendar days, to supply additional requested information. The Commission amended the regulation by extending the time permitted to respond from 10 calendar days to 15 business days.

Next, commenters stated the requests can be voluminous, overly burdensome and outside the scope of review. In response, the Revised Draft extends the number of days for staff to review an application but limits the number of requests permitted. Now, staff must complete the completeness review within 15-20 business days, depending on the type of project. However, staff is now limited to one written request for additional information and one additional request for good cause shown.

Extension of Performance Requirements

The Commission received multiple comments regarding the deletion of COMAR 10.24.01.12E – F, extension of performance requirements. Many commenters voiced concerns about the lack of timeframes and unpredictable factors which may delay deadlines. However, the Draft Regulations allows applicants more flexibility and certainty by allowing the applicant to propose their own schedule for implementation of their project. (See COMAR 10.24.01.12A). Historically, applicants routinely ask for extension requests. The Commission's intent in amending the regulations to allow the applicant to set their own schedule was to hopefully reduce the need to request an extension. However, should an applicant need to seek an extension, they can always do so through COMAR 10.24.01.10A(2).

Emergency CONs

A commenter suggested the Commission amend the emergency CON rules to clarify the duration of the emergency CON. The Revised Draft provides that an emergency CON shall be extended automatically during any period in which the applicant has properly sought a CON to retain the capacity or project approved on an emergency basis. This change recognizes the potential disruption in services without the automatic extension. Additionally, to preserve procedural rights, the Revised Draft permits an emergency CON applicant to seek reconsideration by the Commission if the Executive Director denies an emergency CON.